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OCT 4 2011

Philip S. Johnson, Esq.
Johnson & Johnson
One Johnson & Johnson Plaza
New Brunswick, NJ 08816

In Re: Patent Term Extension
Application for
U.S. Patent No. 5,254,556

Dear Mr Johnson.:

An interim extension under 35 U.S.C. § 156(e)(2) is enclosed extending the term of U.S. Patent No. 5,254,556 for a period of one year from the extended expiration date. While a courtesy copy of this letter is being forwarded to the Food and Drug Administration (FDA), you should directly correspond with the FDA regarding any required changes to the patent expiration dates set forth in the Patent and Exclusivity Data Appendix of the Orange Book (Approved Drug Products with Therapeutic Equivalence Evaluations) or in the Patent Information set forth in the Green Book (FDA Approved Animal Drug Products). Effective August 18, 2003, patent submissions for publication in the Orange Book and Docket *95S-0117 need to be submitted on form FDA-3542 which may be downloaded from FDA's Electronic Forms Download Website:

<http://www.fda.gov/opacom/morechoices/fdaforms/default.html>
(<http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3542.pdf>).

Inquiries regarding this communication should be directed to the undersigned by telephone at (571) 272-7755, or by e-mail at mary.till@uspto.gov.

Mary C. Till
Senior Legal Advisor
Office of Patent Legal Administration
Office of the Associate Commissioner
for Patent Examination Policy

cc: Office of Regulatory Policy
Food and Drug Administration
10903 New Hampshire Ave., Bldg. 51, Rm. 6222
Silver Spring, MD 20993-0002

RE: Invega Sustenna®
Docket No.: FDA-2009-E-0541

Attention: Beverly Friedman

UNITED STATES PATENT AND TRADEMARK OFFICE

In re: Ortho-McNeil-Janssen Pharmaceuticals, Inc. :
Request for Patent Term Extension : ORDER GRANTING
U.S. Patent No. 5,254,556 : INTERIM EXTENSION

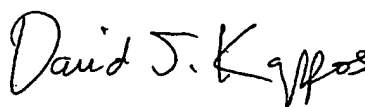
Ortho-McNeil-Janssen Pharmaceuticals, Inc., the owner of record in the United States Patent and Trademark Office (USPTO) of U.S. Patent No. 5,254,556, filed an application for patent term extension under 35 U.S.C. § 156 on August 6, 2009. A second request for interim extension was filed on June 13, 2011. The extended term of the patent expires on October 27, 2011. The patent claims paliperidone palmitate, the active ingredient in the human drug product Invega Sustenna®, which was approved by the Food and Drug Administration for commercial marketing or use on July 31, 2009. An extension of 1,449 days is requested.

The USPTO review to date of the application to date indicates that the subject patent is eligible for extension of the patent term under 35 U.S.C. § 156. A final determination of the length of the extension of the patent term and issuance of a patent term extension certificate cannot be made until a final determination of the length of the regulatory review period is made. Because the extended term of the patent would expire before a certificate of patent term extension can be issued, a second interim extension of the patent term is appropriate.

A second interim extension under 35 U.S.C. § 156(e)(2) of the term of U.S. Patent No. 5,254,556 is granted for a period of one year from the extended expiration date of the patent, i.e., until October 27, 2012.

September 30, 2011

Date



David J. Kappos
Under Secretary of Commerce for Intellectual Property and
Director of the United States Patent and Trademark Office